

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA; THE
STATES OF CALIFORNIA, COLORADO,
CONNECTICUT, DELAWARE, FLORIDA,
GEORGIA, HAWAII, ILLINOIS, INDIANA,
IOWA, LOUISIANA, MARYLAND,
MICHIGAN, MINNESOTA, MONTANA,
NEVADA, NEW JERSEY, NEW MEXICO,
NEW YORK, NORTH CAROLINA,
OKLAHOMA, RHODE ISLAND, TENNESSEE,
TEXAS, WASHINGTON, and WISCONSIN;
THE COMMONWEALTHS OF
MASSACHUSETTS and VIRGINIA; and
THE DISTRICT OF COLUMBIA,

ex rel. MAX BENNETT,

Plaintiffs,

v.

ABIOMED, INC., a Delaware corporation,

Defendant.

CIVIL ACTION NO.:

13-cv-12277-NMG

**FILED IN CAMERA
and UNDER SEAL
pursuant to
31 U.S.C. § 3730(b)(2)**

**PLAINTIFF-RELATOR
DEMANDS TRIAL BY JURY
ON ALL COUNTS**

FIRST AMENDED COMPLAINT

INTRODUCTION

1. Plaintiff-Relator Max Bennett ("Relator") brings this action on behalf
of the United States of America, 28 States¹ ("the Plaintiff States"), and the District of

¹ The 28 "Plaintiff States" on whose behalf Relator brings this action are: California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and Wisconsin.

Columbia (“the District”) to recover monies wrongfully paid by those entities as a result of false and/or fraudulent claims caused by Defendant Abiomed, Inc. (“Abiomed” or “Defendant”). Relator brings this action pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. § 3729, *et seq.*, and pursuant to the *qui tam* provisions of the analog false claims acts of the Plaintiff States and the District (*see* Counts III-XXXI, *infra*). Pursuant to 31 U.S.C. § 3730(b)(2) and comparable state-law provisions, this action is brought *in camera* and under seal.

2. Relator also brings this action in his individual capacity and alleges that Defendant Abiomed unlawfully retaliated against him in violation of federal law, 31 U.S.C. § 3730(h), and Massachusetts law. In particular – and as more fully discussed below – Abiomed wrongfully terminated Relator shortly after he complained to his superiors about what he perceived to be improper conduct by the company.

3. Defendant Abiomed is a medical device company that manufactures and markets mechanical devices (*i.e.*, heart pumps) that assist a patient’s blood flow and/or perform the heart’s pumping function during certain types of heart surgeries and procedures. The company’s most widely-used and commercially-successful devices are the “Impella” line of heart pumps.

4. During his employment at Abiomed, Relator learned that the company was knowingly and deliberately engaging in unlawful conduct to market its medical devices that violated both federal and state “anti-kickback” laws. This unlawful conduct included “wining and dining” and otherwise lavishly entertaining health care providers (physicians, nurses, and other hospital employees and health care providers)

so as to influence their decisions to purchase Abiomed's products. In addition, Abiomed made so-called "*per diem*" payments to hospital and catheter lab workers to cause the purchase of Abiomed's products. Lastly, Abiomed's sales force advocated non-FDA-approved uses for its products – *i.e.*, "off-label marketing" – to increase device sales and resulting revenues for the company.

5. As a result of Abiomed's unlawful conduct, hundreds if not thousands of false and/or fraudulent claims (totaling millions of dollars) were submitted to (and paid by) the United States, the Plaintiff States, and the District for Abiomed medical devices and/or the related medical procedures that used them. That is because Abiomed's unlawful conduct – *i.e.*, violating the "anti-kickback" laws and "off-label marketing" – conclusively tainted those government reimbursement claims and made them ineligible for payment under both federal and state law.

6. Accordingly, Abiomed is liable for knowingly causing these false and/or fraudulent claims to be presented to the United States for payment in violation of 31 U.S.C. § 3729, *et seq.* Abiomed is similarly liable for causing false and/or fraudulent claims to be presented for payment to the Plaintiff States and the District under their respective false claims acts.

THE PARTIES

7. Relator Max Bennett ("Relator") is a United States citizen who resides in Orlando, Florida. He was employed by Defendant Abiomed as its Director of Clinical Operations for the Southeast Region from October 15, 2012, until he was terminated by the company on November 14, 2012. Relator has worked for several companies in

medical device and biotechnology sales and development for over a decade. He earned a Master of Business Administration degree, *Cum Laude*, from Michigan State University in 2002; and a Bachelor of Science degree in Nursing, *Cum Laude*, from Oakland University (Rochester, MI) in 1998. In addition, Relator is a registered nurse ("RN") with active licenses in Florida and Michigan, and with inactive licenses in California, Colorado, and Nevada.

8. Defendant Abiomed, Inc. ("Abiomed") is a Delaware corporation with its principal place of business in Danvers, Massachusetts. Abiomed is in the medical equipment and supplies industry, and it designs, manufactures, and markets a line of medical devices (*i.e.*, "Impella" heart pumps) that are used with patients to improve blood flow and/or to perform the heart's pumping function during certain types of heart surgeries and procedures. Abiomed is a publicly-traded company listed on the NASDAQ with the ticker symbol "ABMD," and with a market capitalization of approximately \$1 billion as of July 24, 2014. Abiomed conducts business on a national scale, marketing its products to hospitals and physicians throughout the United States. For its 2014 fiscal year (ended March 31, 2014), Abiomed reported gross revenue of \$184 million, representing 16% growth from the prior year.

JURISDICTION AND VENUE

9. Pursuant to 28 U.S.C. § 1331, this Court has original jurisdiction over the subject matter of this civil action because it arises under the laws of the United States, in particular the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.* In addition, the FCA specifically confers jurisdiction upon this Court pursuant to 31 U.S.C. § 3732(b).

10. Pursuant to 28 U.S.C. § 1367, this Court has supplemental jurisdiction over the subject matter of the claims brought pursuant to the false claims acts of the Plaintiff States and the District on the grounds that the claims are so related to the claims within this Court's original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution. For the same reason, this Court has supplemental jurisdiction over Relator's employment claims that are based on Massachusetts law.

11. This Court has personal jurisdiction over Abiomed pursuant to 31 U.S.C. § 3732(a) because the FCA authorizes nationwide service of process and Abiomed has sufficient minimum contacts with the United States of America.

12. Venue is proper in this Court pursuant to 31 U.S.C. § 3732(a) because Abiomed is based in and transacts business in this judicial district.

13. Relator is unaware of any public disclosure of the information or allegations that are the basis of the original Complaint filed in this action or this First Amended Complaint. In the event that there has been a public disclosure, Relator is the original source of the information and allegations contained in the original Complaint and the First Amended Complaint. Prior to the filing of this action, Relator voluntarily provided information to the United States regarding the false/fraudulent claims that are the subject of the original Complaint. Relator did so on September 18, 2013. And, prior to filing this First Amended Complaint, Relator voluntarily provided information to the United States, the Plaintiff States, and the District regarding the false/fraudulent claims that are the subject of this pleading on or about July 22, 2014.

GOVERNMENT HEALTH INSURANCE PROGRAMS

14. The Health Insurance for the Aged and Disabled Program, Title XVIII of the Social Security Act, 42 U.S.C. § 1395, *et seq.* (popularly known as “Medicare”), is a health insurance program administered by the United States that is funded by taxpayer revenue. Medicare is overseen by the United States Department of Health and Human Services through its Centers for Medicare and Medicaid Services (“CMS”).

15. Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services, and durable medical equipment for persons over sixty-five (65) years of age; and for certain others that qualify under the terms and conditions of the program, including many individuals who are permanently disabled under the Social Security Act.

16. Reimbursement for Medicare claims is made by the United States through CMS which contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the private insurance carriers act on behalf of CMS.

17. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396–1396v (hereafter “Medicaid”), is a health insurance program administered by the United States and the various individual states that is funded by federal and state taxpayer revenue. The United States uses CMS to oversee Medicaid.

18. Medicaid was designed to assist participating states in providing hospital services, medical services, durable medical equipment, and prescription drugs to, among others, financially-needy individuals that qualify for Medicaid. The states

directly pay providers, with the states obtaining the federal share of the payment from accounts that draw on the United States Treasury. *See* 42 C.F.R. §§ 430.0–430.30 (1994).

19. The Civilian Health and Medical Program of the Uniformed Services (“CHAMPUS” – now known as “TRICARE”), 10 U.S.C. §§ 1071–1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the uniformed services and to spouses and children of active duty, retired, and deceased members. The program is administered by the Department of Defense and funded by the federal government.

20. The federal government, through its Departments of Defense and Veterans Affairs, maintains and operates medical facilities including hospitals, and receives and uses federal funds to purchase medical devices for patients treated at such facilities and otherwise.

21. The Federal Employees Health Benefits Program (“FEHBP”) provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, medical devices for its beneficiaries. (Together, all of the programs described above in paragraphs 14–21, and any other government funded health care programs, shall be referred to as “Government Health Care Programs.”)

22. Reimbursement practices under all Government Health Care Programs closely align with the rules and regulations governing Medicare reimbursement. The most basic requirement for reimbursement eligibility under Medicare, Medicaid, and other Government Health Care Programs is that the service provided must be reasonable and medically necessary. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C.

§ 1396, *et seq.*; 42 C.F.R. § 410.50. Medical providers are not permitted to bill the government for medically unnecessary services or procedures performed solely for the profit of the provider. *See id.*

23. Each of the Government Health Care Programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the Anti-Kickback Statute (discussed below) and with other federal laws governing the provision of health care services in the United States. That agreement represents an ongoing obligation, and the provider must notify the government of any change in information or certifications provided.

24. In other words, if a provider tells CMS or its agent that it provided goods or services in violation of the Anti-Kickback Statute, that were not medically unnecessary, that were performed solely for the profit of the provider, and/or that violated another relevant law, CMS will not pay the claim.

FEDERAL AND STATE ANTI-KICKBACK LAWS

25. The Medicare and Medicaid Patient Protection Act, also known as “the Anti-Kickback Statute,” 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that the remuneration and gifts given to those who can influence health care decisions corrupt medical decision-making and can result in the provision of goods and services that are more expensive and/or medically unnecessary or even harmful to a vulnerable patient population. To protect the integrity of Government Health Care Programs, Congress enacted a prohibition against the payment of kickbacks in any form. The Anti-Kickback Statute was enacted in 1972 “to provide penalties for certain practices

which have long been regarded by professional organizations as unethical, as well as unlawful . . . and which contribute appreciably to the cost of the Medicare and Medicaid programs.” H.R. Rep. No. 92-231, 92d Cong., 1st Sess. 108 (1971), reprinted in 1972 U.S.C.C.A.N. 4989, 5093.

26. In 1977, Congress amended the Anti-Kickback Statute to prohibit receiving or paying “any remuneration” to induce referrals and increased the crime’s severity from a misdemeanor to a felony with a penalty of \$25,000 and/or five years in jail. *See* Social Security Amendment of 1972, Pub. L. No. 92-603, 241(b) and (c); 42 U.S.C. § 1320a-7b. In doing so, Congress noted that the purpose of the Anti-Kickback Statute was to combat fraud and abuse in medical settings that “cheat[] taxpayers who must ultimately bear the financial burden of misuse of funds . . . [that] divert[] from those most in need, the nation’s elderly and poor, scarce program dollars that were intended to provide vitally needed quality health services . . . [and that] erode[] the financial stability of those state and local governments whose budgets are already overextended and who must commit an ever-increasing portion of their financial resources to fulfill the obligations of their medical assistance programs.” H.R. Rep. No. 95-393, pt. 2, at 37, reprinted in 1977 U.S.C.C.A.N. 3039, 3047.²

²Through the amendments Congress sought to “give a clear, loud signal to the thieves and the crooks and the abusers that we [Congress] mean to call a halt to their exploitation of the public and the public purse.” 123 Cong. Rec. S31767 (daily ed. Sept 30, 1997) (statement of Sen. Talmadge).

27. In 1987, Congress again strengthened the Anti-Kickback Statute to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142, Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

28. The Anti-Kickback Statute prohibits any person or entity from knowingly and willfully offering to pay or paying any remuneration to another person to induce that person to purchase, order, or recommend any good, service, or item for which payment may be made in whole or in part by a Government Health Care Program, which includes any state health program funded in part by the federal government. 42 U.S.C. §§ 1320a-7b(b), 1320a-7b(f).

29. The Anti-Kickback Statute provides, in pertinent part:

(b) Illegal remunerations

* * *

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –

(A) To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under Federal health care program, or

(B) To purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

Shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

30. A transaction may violate the Anti-Kickback Statute even when a payor's unlawful intent is not its exclusive intent. It is enough that "*any one purpose* of the remuneration may be to induce or reward the referral or recommendation of business payable in whole or in part by a Federal health care program." OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 3, 2003) (emphasis added). In other words, even "a lawful purpose will not legitimize a payment that also has an unlawful purpose."

31. In addition to criminal penalties, a violation of the Anti-Kickback Statute can also subject the perpetrator to exclusion from participation in Government Health Care Programs (42 U.S.C. § 1320a-7(b)(7)), civil monetary penalties of \$50,000 per violation (42 U.S.C. § 1320a-7a(a)(7)), and three times the amount of remuneration paid, regardless of whether any part of the remuneration is for a legitimate purpose, 42 U.S.C. § 1320a-7a(a).

32. The Anti-Kickback Statute not only prohibits outright bribes and rebate schemes, but also prohibits any payment, gift, or other remuneration by a company to a physician or other person which has as one of its purposes the inducement of the physician to use the company's products or the inducement of the physician to influence or recommend the use of the product.

33. Compliance with the Anti-Kickback Statute is a precondition to participation as a health care provider under Government Health Care Programs, including Medicare and state Medicaid programs. Moreover, compliance with the Anti-Kickback Statute is a *condition of payment* for any claims for which Medicare or Medicaid reimbursement is sought. Every provider who enters into a contract with Medicare specifically acknowledges in its provider contract that the provider understands "that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider]'s compliance with all applicable conditions of participation in Medicare." Upon information and belief, each of the Plaintiff States' and the District's provider agreements in their respective Medicaid programs contains comparable provisions agreeing to comply with the Anti-Kickback Statute and acknowledging that their receipt of payment is conditioned upon compliance with such provisions.

34. Medicare and Medicaid claims for reimbursement of any goods or services that were the subject of a kickback constitute false claims (see False Claims Act discussion, *infra*). This is because compliance with the Anti-Kickback Statute is a precondition to participation as a health care provider under Government Health Care Programs, including Medicare and state Medicaid programs. Moreover, compliance with the Anti-Kickback Statute is a condition of payment for any goods or services

reimbursed by Medicare or Medicaid, including medical devices and related medical procedures using those devices.

35. Furthermore, the Anti-Kickback Statute was amended, effective March 23, 2010, to expressly provide that: “In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act].” Consequently, any kickbacks paid by Abiomed on or after March 23, 2010, that caused reimbursement claims to be presented to the government for payment would result in actionable false claims regardless of the provisions of any provider agreement.

36. When a kickback has been paid, the measure of damages is the full amount of the claim caused by the kickback—such as the amounts billed to Medicare or Medicaid for a kickback-tainted Abiomed medical device and the related medical procedure using that device. All such kickback-tainted payments are owed back to the government. From 2008 through the present, the United States (through Medicare, Medicaid, and other Government Health Care Programs) and the Plaintiff States and the District (through Medicaid) have paid millions of dollars in claims for Abiomed medical devices and related medical procedures that were tainted by Abiomed’s knowingly having paid kickbacks to physicians, hospital and/or catheter lab staff, or others.

FEDERAL AND STATE FALSE CLAIMS ACTS

37. The Federal False Claims Act ("FCA"), 31 U.S.C. § 3729(a)(1)(A), makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment or approval a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between \$5,500 and \$11,000 per claim for claims made on or after September 29, 1999.

38. The FCA, 31 U.S.C. § 3729(a)(1)(B), makes "knowingly" making, using, or causing to be used or made, a false record or statement material to a false or fraudulent claim, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between \$5,500 and \$11,000 per claim for claims made on or after September 29, 1999.

39. The FCA, 31 U.S.C. § 3729(a)(1)(C)), makes any person, who conspires to commit a violation of the FCA, liable for three times the amount of the damages the Government sustains and a civil monetary penalty of between \$5,500 and \$11,000 per claim for claims made on or after September 29, 1999.

40. The FCA defines a "claim" to include any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested. 31 U.S.C. § 3729(b)(2).

41. The FCA, 31 U.S.C. § 3729(b)(1), provides that “(1) the terms ‘knowing’ and ‘knowingly’ – (A) mean that a person, with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud.”

42. The FCA, 31 U.S.C. § 3729(b)(4), provides that “(4) the term ‘material’ means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.”

43. Furthermore, the FCA, 31 U.S.C. § 3730(h), provides relief to employees who have been retaliated against in their employment because of lawful acts done by the employee in furtherance of efforts to stop one or more violations of the FCA. Such retaliation may include discharge, demotion, suspension, threats, harassment or any other type of discrimination in the terms and conditions of employment. The employee is entitled to all relief necessary to make that employee whole, including reinstatement, two times back pay, interest on the back pay, and compensation for any special damages, including litigation costs and reasonable attorneys’ fees.

FACTUAL ALLEGATIONS

I. Defendant Abiomed's Impella Heart Pumps

44. Abiomed's primary focus and largest source of revenue is the "Impella"³ family of products, which include the Impella Recover LP 2.5, Impella CP 2.5, Impella 5.0 LP (inserted through the femoral artery via cutdown), and Impella 5.0 LD (inserted through the aorta). The only difference between the LP and LD versions is the shape of the inflow cannula.

45. The Impella products are minimally invasive heart pump catheters that provide temporary circulatory support. The Impella 2.5 pumps allow for blood flow up to 2.5 liters/minute; the Impella 5.0 pumps allow for blood flow up to 5.0 liters/minute. The Impella products are used with patients to improve blood flow and/or to perform the heart's pumping function during certain types of heart surgeries and procedures.

46. Abiomed's revenues are primarily generated from the sales of Impella products. For its 2014 fiscal year (ended March 31, 2014), Abiomed's Impella products generated \$167 million in revenue, representing almost 91% of Abiomed's worldwide revenue totaling \$184 million. Of that \$167 million in Impella sales, \$152 million were in the United States. Abiomed's other products, which are an insignificant portion of the company sales, include the AbioCor artificial heart.

³ The name Impella is derived from the term "impeller," the rotating component of a centrifugal pump that transfers energy from the motor that drives the pump to the fluid being pumped by accelerating the fluid outwards from the center of rotation.

II. Relator's Employment by Defendant Abiomed

47. Relator Max Bennett is a licensed RN with an MBA and more than ten years of experience working in the medical device industry, especially for companies that market cardiac medical equipment (*e.g.*, pacemakers) to doctors and hospitals. In or about July 2012, Relator was recruited by Abiomed. After Relator went through a thorough interview process, he was hired by Abiomed as its Director of Clinical Operations for the Southeast Region, a position for which he was well qualified given his education, experience, and past employment working for other medical device companies.

48. Relator began working for Abiomed on October 15, 2012. As a Clinical Operations Director, Relator was responsible to ensure that any conduct by him or his coworkers complied with all applicable federal and state laws, particularly with respect to expense accounts, spending limits, and avoiding potential "kickbacks" to physicians, hospital staff, and/or other health care providers or employees.

49. After beginning his employment, Relator was concerned with the lack of internal controls on entertaining health care professionals. On October 17, 2012, just two days after starting with the company, Relator asked Lori Wedge about the company's policy on entertainment spending. Ms. Wedge, the company's Director of Accounting, responded: "Don't worry about the Sunshine Act. ... [it] can be repealed after elections, law is in a draft form, local laws in VT, MA, MN - have limits but that's it."

50. However, as Relator was responsible for approving certain sales representatives' expenditures, this lack of internal controls meant that many of these expenditures could not be justified. Relator therefore requested information from Abiomed regarding the company's policies and procedures governing expense accounts with respect to entertaining health care professionals.

51. Furthermore, Relator soon discovered identifiable violations of the Anti-kickback Statute with respect to Abiomed's hiring practices – *i.e.*, the company was paying unlawful remuneration to hospital and catheter lab employees in return for favored status for Abiomed's products.

52. When Relator identified what he believed to be violations of the False Claims Act and the Anti-kickback Statute, he brought his concerns about Abiomed's practices to his supervisors. For example, on November 5, 2012, Relator emailed David Stevens asking: "Do we have limits on certain things - for instance per dinner \$ per HCP [health care professionals], total number of people at an event, or just a grand total per week per clinical etc ..." That day, Relator received a copy of the Abiomed policy on entertainment. It contained no limits on how much sales representatives could spend on entertaining health care professionals.

53. In addition, Relator was concerned and believed that some of the company's practices did not comply with applicable FDA regulations with respect to off-label marketing of Abiomed's products. He openly asked Dr. David Weber, Abiomed's Chief Operating Officer, whether the company intended to conduct studies to expand the label because he had his own concerns that the company's marketing

campaign was beyond the label. Relator also asked such questions of his direct supervisor David Stevens.

54. Shortly after Relator raised questions about Abiomed's non-compliance with federal law, Abiomed's management questioned Relator regarding his prior employment with Biotronik Inc. (a pacemaker company) and the reasons why he had left. During the course of these discussions, it became obvious to Relator that Abiomed's superiors believed that he had been a whistleblower at his previous company, and therefore they assumed that he would blow the whistle against Abiomed. Abiomed then retaliated against Relator by firing him on November 14, 2012, in violation of both federal and Massachusetts law.

III. Defendant Abiomed's Unlawful Conduct

A. Excessive Entertainment Expenditures - Kickbacks

55. As a Clinical Operations Director for Abiomed, Relator was required to review entertainment expense reports from his subordinates within the company concerning their "wining and dining" of physicians, hospital staff, and/or other health care professionals. These expense reports were supposed to include details as to the identity of the health care professionals who attended the event, the purpose of the event, as well as the amount spent on the program in order for Relator to approve reimbursement. In reviewing the entertainment expense reports submitted to him, Relator witnessed firsthand Abiomed's complete disregard for federal regulations on spending limits with respect to entertaining health care professionals. Relator made

numerous efforts to comply with spending limits with respect to health care professionals and required his coworkers to do the same.

56. Relator first identified the absence and vagueness of entertainment spending limits at Abiomed when on October 18, 2012, during his first full week of employment, he met with Kelly O'Connor, an Abiomed field clinical associate, and asked her about the company's spending policies for doctors and staff. Ms. O'Connor responded: "The company is spending freely; I never had any issues getting reimbursed. We, my husband (a Biotronik representative), did a joint dinner last week. We split the bill – it was over \$8,000. David approved it without any problems." (The "David" to whom she referred was David Stevens, a regional sales director for Abiomed.) When Relator heard these statements from Ms. O'Connor, he told her that he was surprised to hear that because the cardiology and pacemaker industry had become more restrictive with entertainment expenditures that could constitute "kickbacks." Relator's conversation with Ms. O'Connor clearly described and evidenced Abiomed's total disregard for entertainment spending limits.

57. During Relator's first training session in October 2012, he asked Lori Wedge, the director of accounting and the individual running the training, about the government spending limits for health care professionals, physicians, and staff. Ms. Wedge responded with her remark about repealing the Sunshine laws. Ms. Wedge later instructed Relator on completing the attendance portion of the expense reports, and she told him, "if you don't know everybody, list the ones you know, don't fret. No limit on the number of attendees or total sum, or any per-person limit."

58. One of Relator's responsibilities was to approve and sign off on his co-workers' expense reports. On more than one occasion, he reviewed and rejected an expense report because it did not list individuals in attendance or the purpose for the meal. For example, Relator refused to approve a meal at the Watermark Restaurant in Nashville, TN on October 25, 2012. The request for reimbursement for \$1,623.31 did not include any justification for the expense nor did it include any attendees.

59. Relator asked his supervisors for clarity regarding acceptable spending limits, and on November 5, 2012, he emailed his immediate supervisor, David Stevens, Abiomed's Southeast Director of Sales. Rather than answer Relator's questions, Mr. Stevens merely directed Relator to Abiomed's travel and expense policies, which Relator already had reviewed and which provided no guidance on these issues. Relator continued to seek answers from others at Abiomed, but was unsuccessful.

60. In the time that Relator worked for Abiomed, he continually saw excessive entertainment spending by Abiomed on health care professionals. He also saw no effort by the company to limit this illegal conduct. On November 13, 2012, Relator sent an email to Frank LeBlanc, Abiomed's Vice President of Human Resources, expressing his concerns about, *inter alia*: (a) the company's lack of entertainment spending guidelines; (b) comments "by subordinates that the company is 'spending freely'"; and (c) the need for a "Compliance Training Program" to ensure that company employees do not violate applicable laws. The very next day, November 14, 2012, Relator was terminated in retaliation for his efforts to get Abiomed to comply with the anti-kickback laws.

B. “Per diem” Violations – Kickbacks

61. Relator also is aware of unlawful conduct related to “per diem” payments by Abiomed to hospital and/or catheter lab employees. During Relator’s second interview with David Stevens in the first week of September 2012 in Charlotte, North Carolina, the topic of *per diem* use came up in the context of a fairly small number of field staff covering a large territory in the Southeast (28 people covering Florida, Georgia, Alabama, Mississippi, Louisiana, Arkansas, Kentucky, North and South Carolina and Tennessee). During this interview, Mr. Stevens mentioned *per diem* use. Relator advised Mr. Stevens that the pacemaker industry stopped using *per diem* staff a long time ago due to issues with quality of service and the question of how to pay them.

62. Nevertheless, Relator learned that Abiomed routinely paid *per diem* remuneration to hospital and/or catheter lab workers around the country, who were known as “Advocates for Impella.” David Stevens told Relator that paying *per diems* created good will in the hospitals/catheter labs and if the recipient hospital/catheter lab staff responded by successfully influencing the use of Abiomed devices, those people later could be hired as sales representatives. Examples include, Advocate #1 at the Cardiac Catheterization Center, Centennial Medical Center, Nashville, TN (who was later hired full time as an Abiomed sales representative); Advocate #2 at BNHCC Desoto Cath Lab, Southhaven, Mississippi; Advocate #3 with Seton Family Healthcare chain of hospitals in Austin Texas who reported directly to David Stevens. Michael Dyess, former Clinical Operations Director with Abiomed personally managed nine *per*

diem staff. In all, Relator believes that at any one time, Abiomed paid approximately seventy *per diem* staff across America.

63. In addition, Relator overheard a conversation during a company-related presentation to Osceola Regional Medical Center employees and catheter lab staff by Kelly O'Connor at Abuelo's, a restaurant in Kissimmee, Florida, where she was asking volunteers in the room to become an "Impella Advocate." During other conversations with Mr. Stevens and Relator, Mr. Stevens stated that some of the *per diem* staff have strong enough "lab relationships" to generate additional business for Abiomed. Mr. Stevens also told Relator that he wants the clinicians to ask physicians the following types of questions: "How do you define your Impella patient? Have you defined your HR PCI [high risk percutaneous coronary intervention] population? Can we have your next HR PCI patient to show you the benefits of the [Impella] device?" Mr. Stevens told Relator that the *per diem* pay rate Abiomed pays is \$50 per hour.

C. Off-Label Marketing

64. Abiomed's Impella products are not approved by the FDA to treat any condition or to improve outcomes in any specific patient populations because of the lack of clinical trials in humans. Nevertheless, Abiomed ignores the limitation of the Impella labeling and openly admits that its strategy is "is to develop a complete portfolio of products for partial and full circulatory support *to treat acute heart failure patients.*" Indeed, Abiomed's corporate tagline is "Recovering hearts. Saving lives." The Impella products, however, are approved to do neither. The strategy of targeting

acute heart failure patients with the claim that Abiomed's products are "saving lives" is thus misleading and targets off-label sales.

65. Abiomed fraudulently convinces doctors to use its Impella devices over the cheaper and more widely-accepted intra-aortic balloon pump ("IABP"), despite the lack of any proven benefit, a label that does not permit it to make such unsupported claims, and billing rules that require much lower reimbursement rates than Abiomed's customers are instructed to use.

66. Since June 2008, Abiomed has been falsely claiming that its Impella products are superior to IABP, and that Impella products can be used in a broader cross section of patients than the balloon therapy. Abiomed has been touting health benefits of Impella, even though those claimed benefits are either unproven off-label uses or simply false.

67. Abiomed uses false claims of superiority to justify Impella's higher overall device costs. Abiomed recognizes that the high cost of the device means that many physician groups or hospitals would lose money using the device. As a result, Abiomed actively coaches doctors and administrators to falsely code Impella to increase the reimbursement and allow health care providers to boost their profit margins.

68. Despite being Class III Devices, the Impella products have never been subjected to a review of safety and effectiveness by the FDA via the Pre-Market Approval (PMA) process. Rather, they have received market approval via the far less stringent 510(k) clearance process as follows:

<u>Product</u>	<u>Approval Date</u>	<u>510(k) Number</u>
Impella Recover LP 2.5	5/30/08	K063723
Impella 5.0 Catheter Family (5.0 & LD)	4/16/09	K083111
Impella CP (2.5 Plus Catheter)	9/6/12	K112892

69. The Impella Recover LP 2.5 (the “Impella 2.5”) received 510(k) clearance in June 2008 for partial circulatory support for up to six hours. The approved indication for use is:

The IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System is intended for partial circulatory support using an extracorporeal bypass control unit for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

70. The Impella 5.0 (LP) and Impella LD received 510(k) clearance in April 2009 for circulatory support for up to six hours. These devices are larger and provide more blood flow to patients than the Impella 2.5. The approved indication for use is:

The IMPELLA 5.0 Catheters are intended for circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. They are also intended to be used to provide circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

71. The Impella CP received 510(k) clearance September 2012 for partial circulatory support for up to six hours. The Impella CP uses the same platform as the Impella 2.5 but has a slight increase in the diameters of the inflow cannula, impeller, and pump housing. Abiomed claims that these changes result in a 30% increase in blood flow. The approved indication for use is:

The IMPELLA 2.5 PLUS Catheter is intended for partial circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. It is also intended to be used to provide partial

circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

72. Abiomed claims to have placed its Impella products at 859 sites since initial launch.

73. Each of the Impella products marketed in the United States has a similar FDA-approved indication limiting its use “for periods up to 6 hours.” (See ¶¶ 69–71, *supra*.) In contrast, however, the Impella 2.5 has CE mark approval in Europe for up to *five days* of use; and the Impella 5.0 and LD devices have CE mark approval in Europe for up to *ten days* of use. (See Abiomed FY 2014 10-K at 2-4.) The longer duration of use in Europe represents the true intended use of the Impella products. Abiomed obtained the European approval for the 2.5 before it received 510(k) clearance, but the company fraudulently concealed from the FDA the intended use of up to 5 days, piggybacking instead on the 6-hour use of the predicate devices to which Abiomed claimed its device was “substantially equivalent.” In so doing, Abiomed circumvented FDA scrutiny of the multiday use.

74. In June 2008, Abiomed launched the Impella 2.5. Recognizing that the on-label indication in the United States was extremely narrow – especially as compared to the five-day use approved in Europe – Abiomed instructed, coached, and encouraged doctors to use the products in a manner beyond the scope of use the FDA had approved. Specifically, the off-label marketing messages fell into the following categories:

- Stating that Impella is hemodynamically superior to the intra-aortic balloon pump (“IABP”)

- Omitting Impella's 6 hour limitation, or encouraging use greater than 6 hours
- Suggesting the use of Impella in specific types of high-risk patients undergoing high-risk percutaneous coronary intervention
- Misrepresenting the results of the clinical trials
- Encouraging doctors to falsely code or up-code the device so as to increase the reimbursement received

75. As detailed below, Abiomed used false and misleading statements to sell the products. As evidenced by the marketing questions proposed by Mr. Stevens in ¶ 63 above, the goal of Abiomed's marketing strategies was to convince doctors to use Impella products for high-risk percutaneous coronary interventions. This strategy not only required off-label marketing, it also depended on sales representatives deceiving doctors about: (a) the Impella's approved indication; (b) the intended use of the Impella; (c) the approved duration of use for the Impella; (d) the patient populations for whom the Impella was approved; (e) the superiority of the Impella over the established and cheaper treatment using intra-aortic balloon and (f) the amount of reimbursement that could lawfully be received for the Impella. The ultimate goal of all of these false and misleading messages was to shift market share from the balloon to Impella devices.

76. Abiomed's marketing fraud began even before the Impella products were approved by the FDA. In August 2006, Abiomed began conducting the PROTECT I Trial, an open label prospective feasibility trial investigating the use of the Impella 2.5 system in 28 patients undergoing high-risk percutaneous coronary intervention ("The PROTECT I Trial"). The primary aim of the study was to demonstrate that the Impella

2.5 could be safely implanted. The study was not designed to make any conclusions about efficacy or improved health outcomes.

77. The results of the PROTECT I Trial, as presented by Abiomed, showed that the Impella 2.5 could be safely implanted without complications. These results were presented in part at Transcatheter Cardiovascular Therapeutics 2007 conference in Washington, DC held in October 2007.

78. Abiomed submitted a manuscript for publication of the PROTECT I Trial results in *JACC: Cardiovascular Interventions* on October 21, 2008 (five months after the FDA issued the 510(k) clearance), and the journal accepted the manuscript for publication two weeks later.

79. In February 2009, *JACC: Cardiovascular Interventions* published the results of the PROTECT I Trial. Although the study enrolled 28 patients, the published manuscript states falsely that only 20 patients were enrolled. The results of the other 8 patients are not revealed in the published article. Abiomed has never furnished *clinicaltrials.gov* with study results or made the complete results available to the public.

80. Beginning in October 2007, Abiomed began enrolling hundreds of patients for a prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention ("The PROTECT II Trial"). In contrast to the PROTECT I Trial, the PROTECT II Trial was intended to be a large comparative trial comparing outcomes after 30 days between patients on Impella versus intra-aortic balloon pump.

81. About three years into the study, and two-and-a-half years after product launch, interim data based on 327 patients showed that the results of the study would be negative. Based on those results, the PROTECT II's Data and Safety Monitoring Board ("DSMB") recommended that the trial be terminated. On December 6, 2010, the executive committee accepted the recommendation and study enrollment ceased.

82. The trial's failure was a blow to Abiomed's efforts to poach the expansive intra-aortic balloon pump market. The Impella 2.5 device costs approximately \$125,000, whereas the intra-aortic balloon pump that Abiomed seeks to supplant costs only \$1,500. For this reason, the Abiomed sales force repeatedly was instructed to "trade one of yours for one of theirs." Accordingly, Abiomed could not afford to lose in the comparative study between Impella and the balloon pumps.

83. On December 6, 2010, the same day the PROTECT II Trial was halted, Abiomed issued a press release that was intended to favorably spin the negative results as positive. In the press release, Abiomed claimed that investigator confidence with the Impella product—what was termed a desire to "do more with Impella"—resulted in an unexpectedly higher number of atherectomies in the Impella arm of the trial. These atherectomies were the cause of the negative results according to the company. Abiomed claimed that this observation was an "important finding," and the company proceeded to use that to downplay or even to dismiss the negative result of the study. Abiomed's press release also cherry-picked various secondary endpoints and subgroup analyses to find favorable things to say about Impella.

84. On January 28, 2010, the FDA sent Abiomed a letter advising the company that its marketing claims concerning Impella were inappropriate. The FDA specifically objected to an advertisement placed in the September 2010 issue of *Cath Lab Digest* that made comparative claims about the Impella versus the intra-aortic balloon pump that could be interpreted as efficacy statements regarding the superiority of the Impella. Although the PROTECT II Trial had not yet been terminated when the advertisement appeared, the FDA nevertheless pointed out that the comparative claims violated 21 C.F.R. 812.7(d) because companies are prohibited from making representations that a device is safe and effective for the purposes being studied. The ongoing study was cancelled one month later, meaning that if Abiomed made any such comparative statements in the future, they would be intentionally misleading.

85. Abiomed paid consultants to advocate off-label uses for its Impella devices. For example, Brenda McCulloch, a registered nurse who is a paid member of the Abiomed Administrative Advisory Board, published a review article in *Critical Care Nurse* that falsely claimed that Impella was superior to IABP and failed to disclose the early termination of the PROTECT II Trial results. The review article also claimed that Impella could be used for longer than 6 hours, stating that Impella: "is approved for use up to 5 days [in Europe]. Reports of longer duration of therapy in both the United States and Europe have been published." Ms. McCulloch had made similar claims in the Spring 2010 newsletter for Sutter Heart and Vascular Institute of the Sutter, where she stated: "the longest a patient has remained on Impella 5.0 support worldwide is 23 days."

86. Similarly, in February 2011, a paid consultant of Abiomed – Srihari S. Naidu, MD – published a review article in *Circulation* that made numerous unsupported or false claims in favor of Impella products. The article claims that “clinical trials allow use for up to 7 days in the United States and 10 days in Europe.” The article also made numerous superiority claims for the Impella, and suggested numerous off-label indications where Impella supposedly would benefit patients. None of these claims are supported. The article concluded with the claim that “patients undergoing high-risk PCI, those with acute myocardial infarction, and those with higher degrees of heart failure and/or shock may stand to benefit from [novel percutaneous cardiac assist devices such as Impella]”.

87. On June 10, 2011, the FDA sent Abiomed a Warning Letter warning that Abiomed was still making promotional claims that were “inappropriate,” “objectionable,” and represented “a major modification to both the intended use and the indications for use of the device.” Objectionable claims included claims that use of the Impella Recover LP 2.5 in AMI Shock patients improves hemodynamics, and that use of the Impella Recover LP 2.5 improves cardiac output, which is then linked to lower mortality rates. The FDA even noted that Abiomed’s website logo includes the tag line, “Recovering hearts. Saving lives” – which in the absence of clinical data is false and misleading. Because the statements above represented a major change in the intended use of Impella, Abiomed needed a new premarket notification. 21 C.F.R. 807.81(a)(3)(ii). The objectionable claims also meant that the Impella Recover LP 2.5

device was both adulterated and misbranded. Abiomed did not remove the tagline from its website or from its employee business cards.

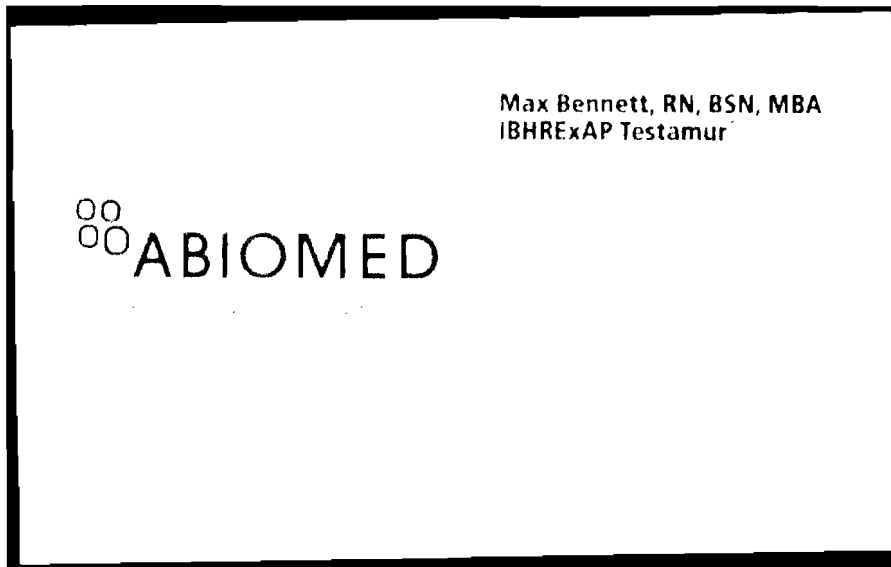
88. That same month, Abiomed revised its Reimbursement Information Sheet that it provides to doctors and health care professionals at the facilities where Impella products were being used. The form was designed to facilitate reimbursement by coaching doctors to identify the off-label manner in which the devices had been used. Most notably, doctors were given a list of “sample MCC and CC’s diagnostic codes” from which to choose. These codes represent the patient’s condition, either a “major complication or comorbidity,” or a “complication or comorbidity.” None of the listed choices was within the FDA labeling:

89. The distribution of the above forms causes the Impella devices to be misbranded under Section 502 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 352, because the labeling is misleading and because it does not bear adequate directions for use.

90. In August 2012, Abiomed caused the results of the PROTECT II Trial to be published in the journal *Circulation*. In a press release, Abiomed hailed the publication of study results, which were negative, to be a “notable achievement” which “will advance the treatment for patients with heart failure.” Abiomed called the study a “landmark” study which “marks a very significant milestone in providing new clinical insight for cardiovascular disease patients considered too risky for conventional surgery.” These statements were misleading because the results were negative, a fact which was concealed in the press release.

91. The full article published in *Circulation* disclosed that the trial had been terminated early due to a futility determination, but nevertheless claimed a trend for Impella’s superior health outcomes emerged after 90 days. This too was a misleading claim.

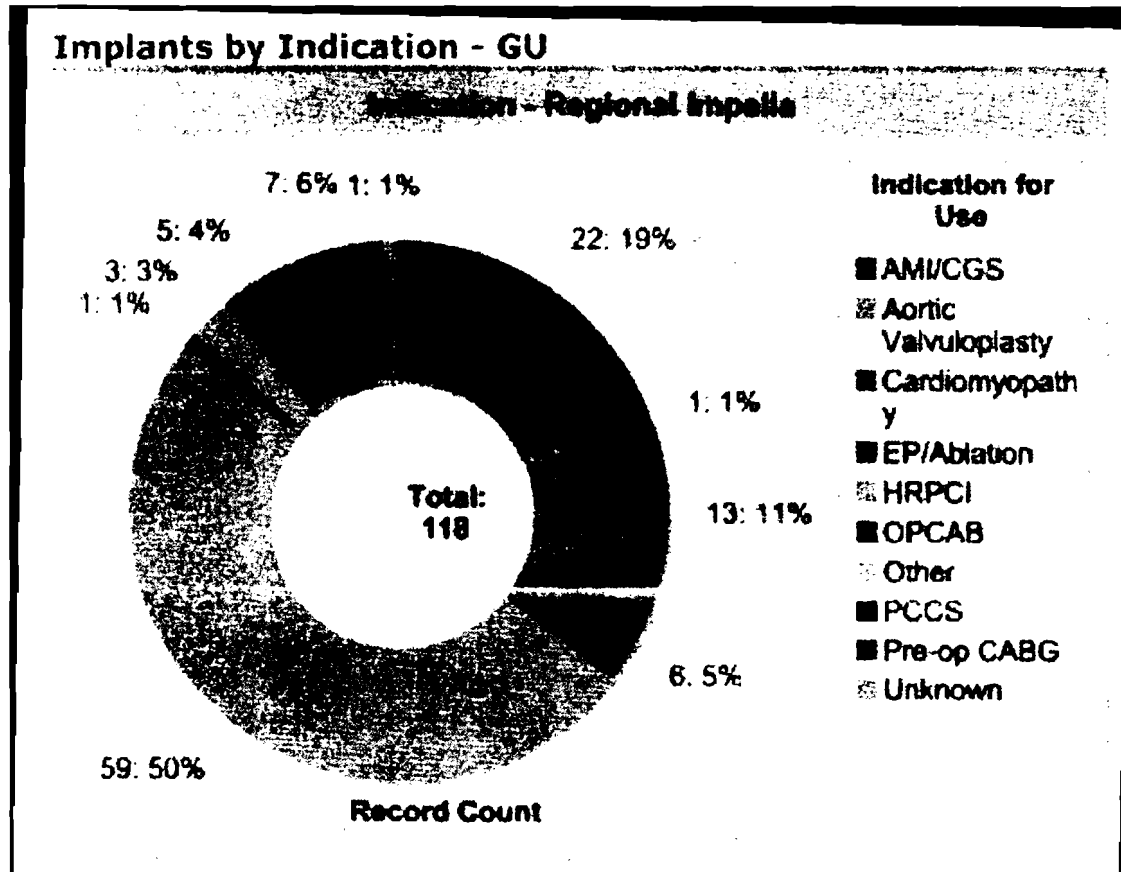
92. In September 2012, Abiomed hired Relator as a Director of Clinical Operations. Abiomed provided Relator with business cards containing the “Recovering hearts. Saving lives” tagline, which according to the FDA was false and misleading:



93. Other Abiomed employees also carried business cards with the same prohibited language - *e.g.*, Lori Wedge, Director of Accounting. However, because Relator first was employed four months after the FDA warning letter, Abiomed cannot be excused for the newly-printed business cards given to Relator as being a vestige of an earlier era. Indeed, as of July 24, 2014, Abiomed's website still displays the improper "Recovering hearts. Saving lives" slogan.

94. Upon starting work for Abiomed, Relator soon learned that the company was instructing employees to collect data on how doctors used Impella in surgery. Employees were able to do this because they were directly involved in scheduling cases. Through an outside company called Salesforce.com, Abiomed collected the reported data and then provided it in report form to all employees so that they could monitor how the Impella devices were being used. Abiomed uses Salesforce.com as a centralized source for all sales data and tacking data. On a daily basis, Abiomed

employees receive via email sales data such as the following chart, which shows that the majority of Impella's uses are off-label:



95. Similarly, Abiomed tracked its success in illegally marketing the extended use of Impella devices beyond their six-hour limit. The company circulated Salesforce.com data in an internal report called the "Impella on Support Report" to field employees, which included sales managers, clinical directors, sales reps, clinical reps, and other employees whose function is to interact with physician customers. The Impella on Support Report listed the length of time patients received "support" from Impella devices. Significantly, the report measured time in days, not hours. In one such report circulated on October 25, 2012, 18 of 22 patients had been on Impella

support for more than 1 day; half had been on Impella support for more than 4 days; and one patient at the Ochsner Foundation Hospital in New Orleans had been on an Impella device for 17 days.

96. On October 26, 2012 – during Relator’s employment at Abiomed – the United States Attorney’s Office for the District of Columbia informed Abiomed that it was conducting an investigation of the company’s marketing and labeling of the Impella 2.5. And, on October, 31, 2012, Abiomed accepted service of a Health Insurance Portability and Accountability Act administrative subpoena related to this investigation.

97. After the subpoena was received, Abiomed’s senior management conducted a series of conference calls ostensibly to address employee concerns but in actuality to minimize the perception that a federal investigation was a bad sign, manage the possible anxiety of employees who were worried about where the investigation was headed, and to prevent attrition of staff. These calls were done in a “top-down” fashion, meaning that Abiomed communicated its message incrementally throughout the company to control the flow of information.

98. At a conference call led by Mike Howley, Abiomed’s VP in charge of global sales and marketing, Relator observed that marketing violations can very often be remedied by conducting studies. Relator then asked Abiomed’s Chief Operating Officer, Dr. David Weber: “Since our products seem to have expanded their use, do we have plans to conduct clinical studies to expand indications and alleviate any off label marketing risks and concerns?” Dr. Weber’s response to this question was evasive,

stating that the company did have plans for clinical studies to expand the indications, but failing to provide any details about the timing or content of such studies – thus casting doubt as to the truth of his assertion.

99. On November 1, 2012, Abiomed issued a press release admitting the existence of the federal investigation and subpoena. Abiomed also stated that it was expecting the FDA to hold an Advisory Panel in early December 2012 to review the classification determination of intra-aortic balloon pumps and nonroller-type cardiopulmonary bypass blood pumps, including Impella products.

100. Two weeks after the subpoena, Abiomed terminated Relator on November 14, 2012.

101. On December 6, 2012, the FDA's Circulatory System Devices Panel held a meeting to determine whether temporary ventricular support devices within the non-roller type cardiopulmonary bypass blood pumps category, including Impella products, should retain Class III status. Abiomed's COO Dr. David Weber, Dr. Jeffrey Popma of Beth Israel Deaconess Medical Center in Boston, and Dr. William O'Neill of Henry Ford Hospital led a presentation on Impella devices. Their remarks, as indicated by the slides used, repeated the same misrepresentations above, including the spinning of the PROTECT II Trial study results.

Clinical Summary: Objectives-I

- FDA Executive Summary identified 5 studies using the Impella 2.5 device, comprising 231 patients undergoing HR-PCI. We would request that the Panel also consider additional analyses published after the 2011 ACC/AHA/SCAI guidelines not included in the FDA Summary.
- O'Neill et al The PROTECT II study. Circ 2012;126(14):1717-27.
 - Dangas et al (abstr). J Am Coll Cardiol 2012;60:B21
 - Popma et al. (abstr). J Am Coll Cardiol 2012;59:A372
- The USpella Registry. CCI 2012;80(5):717-25.

Clinical Summary: Objectives-II

- FDA Executive Summary provides a preliminary overview of the primary endpoint of the PROTECT-II study as described by the DSMB. We would request that the Advisory Panel also consider:
 - PROTECT-II Pre-defined analysis population (PP)
 - PROTECT-II: Four pre-defined subgroup analyses
 - Other Registries and post-hoc analyses that describe the *totality* of clinical evidence supporting the reasonable safety and efficacy of the Impella 2.5

102. Despite this presentation, the FDA's Circulatory System Devices Panel voted to retain Class III status for the temporary ventricular support devices within the

non-roller type cardiopulmonary bypass blood pumps category, including Impella products. Abiomed issued a press release announcing the result that day.

103. On September 13, 2013, Abiomed entered into a tolling agreement with the United States Attorney's Office, pursuant to which it and the United States Attorney's Office mutually agreed to toll the applicable statutes of limitations for all criminal, civil and administrative offenses and violations that could be charged or claimed against Abiomed as of that date until June 2, 2014.

104. Relator commenced this action on September 18, 2013.

105. In January 2014, a group of authors including those with financial relationships with Abiomed published an article encouraging the use of Impella for off-label uses. Most significantly, the article advocated use of Impella for a large number of patients undergoing coronary artery bypass grafting, an indication clearly excluded from the label. The article also made comparative claims, even though the study being presented was retrospective, open-label, and made no comparisons. The article concluded with unsupported and dubious claims of improved survival with Impella.

106. In January 2014, Abiomed published a second article of data from the PROTECT II Trial. This article, published in *The American Journal of Cardiology*, was a post-hoc statistical reanalysis of the PROTECT II Trial which claimed that Impella led to improved health outcomes over intra-aortic balloon pumps.

107. In April 2014, Abiomed published yet another post-hoc statistical reanalysis of the PROTECT II Trial, again claiming that Impella led to improved health outcomes over the intra-aortic balloon pumps. This reanalysis was published in

American Heart Journal. All but two of the article's authors have received either research grants, speaker honoraria, or consultancy fees from Abiomed.

108. On April 25, 2014, the Boston regional office of the United States Department of Health and Human Services, Office of Inspector General served a subpoena on Abiomed regarding its reimbursement and remuneration to healthcare providers. Abiomed's CEO Mike Minogue stated in a press release that the subpoena issued by the Boston regional office was national in scope and covered payments made to healthcare providers from July 2012 to December 2012.

109. On May 27, 2014, Abiomed executed an extension of the tolling agreement with the United States Attorney's Office through February 2, 2015.

IV. Defendant Abiomed's Retaliation Against Relator

110. During the time that Relator was employed by Abiomed, he discovered examples of the company engaging in excessive entertainment spending on health care professionals, and otherwise engaging in what he reasonably perceived to be violations of the federal Anti-Kickback Statute, including unlawful "*per diem*" payments. Relator expressly raised his concerns to company executives on several occasions. Most notably, on November 13, 2012, Relator sent an email to Frank LeBlanc, Abiomed's Vice President of Human Resources, expressing his concerns about, *inter alia*: (a) the company's lack of entertainment spending guidelines; (b) comments "by subordinates that the company is 'spending freely'"; and (c) the need for a "Compliance Training Program" to ensure that company employees do not violate applicable laws. The very

next day, November 14, 2012, Relator was terminated in retaliation for, *inter alia*, his efforts to get Abiomed to comply with the anti-kickback laws.

LEGAL CLAIMS FOR RELIEF

111. Relator alleges that Defendant Abiomed's conduct detailed above violates the Federal False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.* (Counts I & II), and violates the analogous false claims acts of the Plaintiff States and the District (Counts III-XXXI). He brings these claims on behalf of the United States, the Plaintiff States, and the District, as well as on his own behalf. In addition, he brings personal claims against Defendant for retaliating against him in violation of 31 U.S.C. § 3730(h) (Count XXXII), and in violation of Massachusetts law (Counts XXXIII & XXXIV).

CLAIMS ON BEHALF OF THE UNITED STATES

COUNT I

Federal False Claims Act

31 U.S.C. § 3729, *et seq.*

False Claims Based on Illegal Kickbacks

112. Relator repeats and realleges the allegations set forth in paragraphs 1 through 111 as if fully set forth herein.

113. This is a claim for treble damages and penalties against Defendant Abiomed under the Federal False Claims Act, 31 U.S.C. § 3729, *et seq.*

114. As described above, Defendant Abiomed provided unlawful financial inducements to health care providers to generate sales of Defendant's products in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). Such financial inducements included, without limitation, "*per diem*" payments to hospital and catheter

lab employees, and excessive expenditures for “wining and dining” and/or otherwise entertaining physicians and/or other health care providers.

115. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the United States, in violation of federal law.

116. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the United States to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of federal law.

117. The United States – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant’s conduct as alleged herein.

118. By reason of Defendant Abiomed’s conduct, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

119. Pursuant to federal law, the United States is entitled to three times the amount of actual damages, plus the maximum penalty of \$11,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

120. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by federal law, Relator is entitled to a "relator's share" of any recovery obtained by the United States as a result of this claim.

COUNT II
Federal False Claims Act
31 U.S.C. § 3729, *et seq.*
False Claims Based on Off-Label Marketing

121. Relator repeats and realleges the allegations set forth in paragraphs 1 through 120 as if fully set forth herein.

122. This is a claim for treble damages and penalties against Defendant Abiomed under the Federal False Claims Act, 31 U.S.C. § 3729, *et seq.*

123. As described above, Defendant Abiomed engaged in unlawful off-label marketing to generate sales of Defendant's products in violation of federal law. Such off-label marketing included, without limitation, advocating use of Abiomed's Impella products for time periods longer than six hours, despite the fact that the FDA never has approved Impella's products for such extended use, stating that Impella is hemodynamically superior to the intra-aortic balloon pump, and the use of Impella in specific types of patients undergoing high-risk percutaneous coronary intervention.

124. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the United States, in violation of federal law.

125. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the United States to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of federal law.

126. The United States – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

127. Abiomed's off-label marketing described above has also caused the Impella products to be misbranded, thus making their introduction into interstate commerce illegal and their access to federal reimbursement.

128. By reason of Defendant Abiomed's conduct, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

129. Pursuant to federal law, the United States is entitled to three times the amount of actual damages, plus the maximum penalty of \$11,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

130. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by federal law, Relator is entitled to

a “relator’s share” of any recovery obtained by the United States as a result of this claim.

CLAIMS ON BEHALF OF THE PLAINTIFF STATES AND THE DISTRICT

COUNT III

California False Claims Act
Cal. Gov’t. Code § 12650, *et seq.*

131. Relator repeats and realleges the allegations set forth in paragraphs 1 through 130 as if fully set forth herein.

132. This is a claim for treble damages and penalties against Defendant Abiomed under the California False Claims Act, Cal. Gov’t. Code § 12650, *et seq.*

133. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of California, in violation of California law.

134. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of California to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of California law.

135. The State of California – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant’s conduct as alleged herein.

136. By reason of Defendant Abiomed's conduct, the State of California has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

137. Pursuant to California law, the State of California is entitled to three times the amount of actual damages, plus the maximum penalty of \$10,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

138. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by California law, Relator is entitled to a "relator's share" of any recovery obtained by the State of California (and/or the federal government) as a result of this claim.

COUNT IV

Colorado Medicaid False Claims Act Col. Rev. Stat. § 25.5-4-303.5, *et seq.*

139. Relator repeats and realleges the allegations set forth in paragraphs 1 through 138 as if fully set forth herein.

140. This is a claim for treble damages and penalties against Defendant Abiomed under the Colorado Medicaid False Claims Act, Col. Rev. Stat. § 25.5-4-303.5, *et seq.*

141. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Colorado, in violation of Colorado law.

142. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Colorado to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Colorado law.

143. The State of Colorado – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant’s conduct as alleged herein.

144. By reason of Defendant Abiomed’s conduct, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

145. Pursuant to Colorado law, the State of Colorado is entitled to three times the amount of actual damages, plus the maximum penalty of \$10,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

146. In addition, Relator is entitled to his costs of suit and attorneys’ fees incurred in bringing this action. And, as provided by Colorado law, Relator is entitled to a “relator’s share” of any recovery obtained by the State of Colorado (and/or the federal government) as a result of this claim.

COUNT V

Connecticut False Claims Act
Conn. Gen. Stat. §17b-301a, *et seq.*

147. Relator repeats and realleges the allegations set forth in paragraphs 1 through 146 as if fully set forth herein.

148. This is a claim for treble damages and penalties against Defendant Abiomed under the Connecticut False Claims Act, Conn. Gen. Stat. §17b-301a, *et seq.*

149. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Connecticut, in violation of Connecticut law.

150. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Connecticut to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Connecticut law.

151. The State of Connecticut – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

152. By reason of Defendant Abiomed's conduct, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

153. Pursuant to Connecticut law, the State of Connecticut is entitled to three times the amount of actual damages, plus the maximum penalty of \$10,000, for each

and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

154. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by Connecticut law, Relator is entitled to a "relator's share" of any recovery obtained by the State of Connecticut (and/or the federal government) as a result of this claim.

COUNT VI
Delaware False Claims and False Reporting Act
6 Del. C. § 1201, *et seq.*

155. Relator repeats and realleges the allegations set forth in paragraphs 1 through 154 as if fully set forth herein.

156. This is a claim for treble damages and penalties against Defendant Abiomed under the Delaware False Claims and False Reporting Act, 6 Del. C. § 1201, *et seq.*

157. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Delaware, in violation of Delaware law.

158. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Delaware to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Delaware law.

159. The State of Delaware – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant’s conduct as alleged herein.

160. By reason of Defendant Abiomed’s conduct, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

161. Pursuant to Delaware law, the State of Delaware is entitled to three times the amount of actual damages, plus the maximum penalty of \$11,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

162. In addition, Relator is entitled to his costs of suit and attorneys’ fees incurred in bringing this action. And, as provided by Delaware law, Relator is entitled to a “relator’s share” of any recovery obtained by the State of Delaware (and/or the federal government) as a result of this claim.

COUNT VII
District of Columbia Procurement Act
D.C. Code § 2-308.13, *et seq.*

163. Relator repeats and realleges the allegations set forth in paragraphs 1 through 162 as if fully set forth herein.

164. This is a claim for treble damages and penalties against Defendant Abiomed under the District of Columbia Procurement Act, D.C. Code § 2-308.13, *et seq.*

165. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the District of Columbia, in violation of District of Columbia law.

166. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the District of Columbia to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of District of Columbia law.

167. The District of Columbia – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

168. By reason of Defendant Abiomed's conduct, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

169. Pursuant to District of Columbia law, the District of Columbia is entitled to three times the amount of actual damages, plus the maximum penalty of \$10,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

170. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by District of Columbia law, Relator

is entitled to a “relator’s share” of any recovery obtained by the District of Columbia (and/or the federal government) as a result of this claim.

COUNT VIII

Florida False Claims Act
Fla. Stat. Ann. § 68.081, *et seq.*

171. Relator repeats and realleges the allegations set forth in paragraphs 1 through 170 as if fully set forth herein.

172. This is a claim for treble damages and penalties against Defendant Abiomed under the Florida False Claims Act, Fla. Stat. Ann. § 68.081, *et seq.*

173. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Florida, in violation of Florida law.

174. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Florida to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Florida law.

175. The State of Florida – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant’s conduct as alleged herein.

176. By reason of Defendant Abiomed’s conduct, the State of Florida has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

177. Pursuant to Florida law, the State of Florida is entitled to three times the amount of actual damages, plus the maximum penalty of \$11,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

178. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by Florida law, Relator is entitled to a "relator's share" of any recovery obtained by the State of Florida (and/or the federal government) as a result of this claim.

COUNT IX
Georgia False Medicaid Claims Act
Ga. Code Ann. § 49-4-168, *et seq.*

179. Relator repeats and realleges the allegations set forth in paragraphs 1 through 178 as if fully set forth herein.

180. This is a claim for treble damages and penalties against Defendant Abiomed under the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168, *et seq.*

181. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Georgia, in violation of Georgia law.

182. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the

State of Georgia to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Georgia law.

183. The State of Georgia – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant’s conduct as alleged herein.

184. By reason of Defendant Abiomed’s conduct, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

185. Pursuant to Georgia law, the State of Georgia is entitled to three times the amount of actual damages, plus the maximum penalty of \$11,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

186. In addition, Relator is entitled to his costs of suit and attorneys’ fees incurred in bringing this action. And, as provided by Georgia law, Relator is entitled to a “relator’s share” of any recovery obtained by the State of Georgia (and/or the federal government) as a result of this claim.

COUNT X
Hawaii False Claims Act
Haw. Rev. Stat. § 661-21, *et seq.*

187. Relator repeats and realleges the allegations set forth in paragraphs 1 through 186 as if fully set forth herein.

188. This is a claim for treble damages and penalties against Defendant Abiomed under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21, *et seq.*

189. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Hawaii, in violation of Hawaii law.

190. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Hawaii to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Hawaii law.

191. The State of Hawaii – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

192. By reason of Defendant Abiomed's conduct, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

193. Pursuant to Hawaii law, the State of Hawaii is entitled to three times the amount of actual damages, plus the maximum penalty of \$10,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

194. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by Hawaii law, Relator is entitled to a "relator's share" of any recovery obtained by the State of Hawaii (and/or the federal government) as a result of this claim.

COUNT XI
Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. § 175/1, et seq.

195. Relator repeats and realleges the allegations set forth in paragraphs 1 through 194 as if fully set forth herein.

196. This is a claim for treble damages and penalties against Defendant Abiomed under the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1, et seq.

197. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Illinois, in violation of Illinois law.

198. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Illinois to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Illinois law.

199. The State of Illinois – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

200. By reason of Defendant Abiomed's conduct, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

201. Pursuant to Illinois law, the State of Illinois is entitled to three times the amount of actual damages, plus the maximum penalty of \$11,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

202. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by Illinois law, Relator is entitled to a "relator's share" of any recovery obtained by the State of Illinois (and/or the federal government) as a result of this claim.

COUNT XII

Indiana False Claims and Whistleblower Protection Act Ind. Code Ann. § 5-11-5.5-1, *et seq.*

203. Relator repeats and realleges the allegations set forth in paragraphs 1 through 202 as if fully set forth herein.

204. This is a claim for treble damages and penalties against Defendant Abiomed under the Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. § 5-11-5.5-1, *et seq.*

205. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Indiana, in violation of Indiana law.

206. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Indiana to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Indiana law.

207. The State of Indiana – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

208. By reason of Defendant Abiomed's conduct, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

209. Pursuant to Indiana law, the State of Indiana is entitled to three times the amount of actual damages, plus the maximum penalty of \$5,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

210. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by Indiana law, Relator is entitled to a "relator's share" of any recovery obtained by the State of Indiana (and/or the federal government) as a result of this claim.

COUNT XIII
Iowa Medicaid False Claims Act
Iowa Code § 685, *et seq.*

211. Relator repeats and realleges the allegations set forth in paragraphs 1 through 210 as if fully set forth herein.

212. This is a claim for treble damages and penalties against Defendant Abiomed under the Iowa Medicaid False Claims Act, Iowa Code § 685, *et seq.*

213. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Iowa, in violation of Iowa law.

214. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Iowa to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Iowa law.

215. The State of Iowa – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

216. By reason of Defendant Abiomed's conduct, the State of Iowa has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

217. Pursuant to Iowa law, the State of Iowa is entitled to three times the amount of actual damages, plus the maximum penalty of \$10,000, for each and every

false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

218. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by Iowa law, Relator is entitled to a "relator's share" of any recovery obtained by the State of Iowa (and/or the federal government) as a result of this claim.

COUNT XIV

Louisiana Medical Assistance Programs Integrity Law 46 La. Rev. Stat., ch. 3 § 437.1, *et seq.*

219. Relator repeats and realleges the allegations set forth in paragraphs 1 through 218 as if fully set forth herein.

220. This is a claim for treble damages and penalties against Defendant Abiomed under the Louisiana Medical Assistance Programs Integrity Law, 46 La. Rev. Stat., ch. 3 § 437.1, *et seq.*

221. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Louisiana, in violation of Louisiana law.

222. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Louisiana to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Louisiana law.

223. The State of Louisiana – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant’s conduct as alleged herein.

224. By reason of Defendant Abiomed’s conduct, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

225. Pursuant to Louisiana law, the State of Louisiana is entitled to three times the amount of actual damages, plus the maximum penalty of \$10,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

226. In addition, Relator is entitled to his costs of suit and attorneys’ fees incurred in bringing this action. And, as provided by Louisiana law, Relator is entitled to a “relator’s share” of any recovery obtained by the State of Louisiana (and/or the federal government) as a result of this claim.

COUNT XV

Maryland False Health Claims Act
Md. Code Ann., Health-Gen. § 2-601, *et seq.*

227. Relator repeats and realleges the allegations set forth in paragraphs 1 through 226 as if fully set forth herein.

228. This is a claim for treble damages and penalties against Defendant Abiomed under the Maryland False Health Claims Act, Md. Code Ann., Health-Gen. § 2-601, *et seq.*

229. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Maryland, in violation of Maryland law.

230. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Maryland to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Maryland law.

231. The State of Maryland – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

232. By reason of Defendant Abiomed's conduct, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

233. Pursuant to Maryland law, the State of Maryland is entitled to three times the amount of actual damages, plus the maximum penalty of \$10,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

234. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by Maryland law, Relator is entitled to a "relator's share" of any recovery obtained by the State of Maryland (and/or the federal government) as a result of this claim.

COUNT XVI

Massachusetts False Claims Law
Mass. Gen. Laws, ch. 12 § 5A, *et seq.*

235. Relator repeats and realleges the allegations set forth in paragraphs 1 through 234 as if fully set forth herein.

236. This is a claim for treble damages and penalties against Defendant Abiomed under the Massachusetts False Claims Law, Mass. Gen. Laws, ch. 12 § 5A, *et seq.*

237. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the Commonwealth of Massachusetts, in violation of Massachusetts law.

238. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the Commonwealth of Massachusetts to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Massachusetts law.

239. The Commonwealth of Massachusetts – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

240. By reason of Defendant Abiomed's conduct, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

241. Pursuant to Massachusetts law, the Commonwealth of Massachusetts is entitled to three times the amount of actual damages, plus the maximum penalty of \$10,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

242. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by Massachusetts law, Relator is entitled to a "relator's share" of any recovery obtained by the Commonwealth of Massachusetts (and/or the federal government) as a result of this claim.

COUNT XVII

Michigan Medicaid False Claim Act
Mich. Comp. Laws § 400.601, *et seq.*

243. Relator repeats and realleges the allegations set forth in paragraphs 1 through 242 as if fully set forth herein.

244. This is a claim for treble damages and penalties against Defendant Abiomed under the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601, *et seq.*

245. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Michigan, in violation of Michigan law.

246. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Michigan to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Michigan law.

247. The State of Michigan – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant’s conduct as alleged herein.

248. By reason of Defendant Abiomed’s conduct, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

249. Pursuant to Michigan law, the State of Michigan is entitled to three times the amount of actual damages, plus the maximum penalty of \$10,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

250. In addition, Relator is entitled to his costs of suit and attorneys’ fees incurred in bringing this action. And, as provided by Michigan law, Relator is entitled to a “relator’s share” of any recovery obtained by the State of Michigan (and/or the federal government) as a result of this claim.

COUNT XVIII
Minnesota False Claims Act
Minn. Stat. § 15C.01, *et seq.*

251. Relator repeats and realleges the allegations set forth in paragraphs 1 through 250 as if fully set forth herein.

252. This is a claim for treble damages and penalties against Defendant Abiomed under the Minnesota False Claims Act, Minn. Stat. § 15C.01, *et seq.*

253. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Minnesota, in violation of Minnesota law.

254. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Minnesota to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Minnesota law.

255. The State of Minnesota – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

256. By reason of Defendant Abiomed's conduct, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

257. Pursuant to Minnesota law, the State of Minnesota is entitled to three times the amount of actual damages, plus the maximum penalty of \$11,000, for each

and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

258. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by Minnesota law, Relator is entitled to a "relator's share" of any recovery obtained by the State of Minnesota (and/or the federal government) as a result of this claim.

COUNT XIX
Montana False Claims Act
Mont. Code Ann. § 17-8-401, *et. seq.*

259. Relator repeats and realleges the allegations set forth in paragraphs 1 through 258 as if fully set forth herein.

260. This is a claim for treble damages and penalties against Defendant Abiomed under the Montana False Claims Act, Mont. Code Ann. § 17-8-401, *et seq.*

261. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Montana, in violation of Montana law.

262. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Montana to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Montana law.

263. The State of Montana - unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented,

by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant’s conduct as alleged herein.

264. By reason of Defendant Abiomed’s conduct, the State of Montana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

265. Pursuant to Montana law, the State of Montana is entitled to three times the amount of actual damages, plus the maximum penalty of \$10,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

266. In addition, Relator is entitled to his costs of suit and attorneys’ fees incurred in bringing this action. And, as provided by Montana law, Relator is entitled to a “relator’s share” of any recovery obtained by the State of Montana (and/or the federal government) as a result of this claim.

COUNT XX

Nevada False Claims Act
Nev. Rev. Stat. Ann. § 357.010, *et seq.*

267. Relator repeats and realleges the allegations set forth in paragraphs 1 through 266 as if fully set forth herein.

268. This is a claim for treble damages and penalties against Defendant Abiomed under the Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.010, *et seq.*

269. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Nevada, in violation of Nevada law.

270. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Nevada to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Nevada law.

271. The State of Nevada – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

272. By reason of Defendant Abiomed's conduct, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

273. Pursuant to Nevada law, the State of Nevada is entitled to three times the amount of actual damages, plus the maximum penalty of \$10,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

274. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by Nevada law, Relator is entitled to

a “relator’s share” of any recovery obtained by the State of Nevada (and/or the federal government) as a result of this claim.

COUNT XXI

New Jersey False Claims Act
N.J. Stat. § 2A:32C-1, *et seq.*

275. Relator repeats and realleges the allegations set forth in paragraphs 1 through 274 as if fully set forth herein.

276. This is a claim for treble damages and penalties against Defendant Abiomed under the New Jersey False Claims Act, N.J. Stat. § 2A:32C-1, *et seq.*

277. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of New Jersey, in violation of New Jersey law.

278. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of New Jersey to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of New Jersey law.

279. The State of New Jersey – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant’s conduct as alleged herein.

280. By reason of Defendant Abiomed’s conduct, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

281. Pursuant to New Jersey law, the State of New Jersey is entitled to three times the amount of actual damages, plus the maximum penalty of \$11,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

282. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by New Jersey law, Relator is entitled to a "relator's share" of any recovery obtained by the State of New Jersey (and/or the federal government) as a result of this claim.

COUNT XXII

New Mexico Medicaid False Claims Act
N.M. Stat. Ann. § 27-14-1, *et seq.*

283. Relator repeats and realleges the allegations set forth in paragraphs 1 through 282 as if fully set forth herein.

284. This is a claim for treble damages and penalties against Defendant Abiomed under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1, *et seq.*

285. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of New Mexico, in violation of New Mexico law.

286. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the

State of New Mexico to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of New Mexico law.

287. The State of New Mexico – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant’s conduct as alleged herein.

288. By reason of Defendant Abiomed’s conduct, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

289. Pursuant to New Mexico law, the State of New Mexico is entitled to three times the amount of actual damages, plus the maximum penalty of \$10,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

290. In addition, Relator is entitled to his costs of suit and attorneys’ fees incurred in bringing this action. And, as provided by New Mexico law, Relator is entitled to a “relator’s share” of any recovery obtained by the State of New Mexico (and/or the federal government) as a result of this claim.

COUNT XXIII
New York False Claims Act
N.Y. State Fin. § 187, *et seq.*

291. Relator repeats and realleges the allegations set forth in paragraphs 1 through 290 as if fully set forth herein.

292. This is a claim for treble damages and penalties against Defendant Abiomed under the New York False Claims Act, N.Y. State Fin. § 187, *et seq.*

293. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of New York, in violation of New York law.

294. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of New York to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of New York law.

295. The State of New York – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

296. By reason of Defendant Abiomed's conduct, the State of New York has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

297. Pursuant to New York law, the State of New York is entitled to three times the amount of actual damages, plus the maximum penalty of \$12,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

298. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by New York law, Relator is entitled to a "relator's share" of any recovery obtained by the State of New York (and/or the federal government) as a result of this claim.

COUNT XXIV
North Carolina False Claims Act
N.C. Gen. Stat. § 1-605, *et seq.*

299. Relator repeats and realleges the allegations set forth in paragraphs 1 through 298 as if fully set forth herein.

300. This is a claim for treble damages and penalties against Defendant Abiomed under the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605, *et seq.*

301. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of North Carolina, in violation of North Carolina law.

302. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of North Carolina to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of North Carolina law.

303. The State of North Carolina – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

304. By reason of Defendant Abiomed's conduct, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

305. Pursuant to North Carolina law, the State of North Carolina is entitled to three times the amount of actual damages, plus the maximum penalty of \$11,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

306. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by North Carolina law, Relator is entitled to a "relator's share" of any recovery obtained by the State of North Carolina (and/or the federal government) as a result of this claim.

COUNT XXV
Oklahoma Medicaid False Claims Act
Okla. Stat., tit. 63 § 5053, *et seq.*

307. Relator repeats and realleges the allegations set forth in paragraphs 1 through 306 as if fully set forth herein.

308. This is a claim for treble damages and penalties against Defendant Abiomed under the Oklahoma Medicaid False Claims Act, Okla. Stat., tit. 63 § 5053, *et seq.*

309. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Oklahoma, in violation of Oklahoma law.

310. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Oklahoma to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Oklahoma law.

311. The State of Oklahoma – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

312. By reason of Defendant Abiomed's conduct, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

313. Pursuant to Oklahoma law, the State of Oklahoma is entitled to three times the amount of actual damages, plus the maximum penalty of \$10,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

314. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by Oklahoma law, Relator is entitled to a "relator's share" of any recovery obtained by the State of Oklahoma (and/or the federal government) as a result of this claim.

COUNT XXVI
Rhode Island False Claims Act
R.I. Gen. Laws § 9-1.1-1, *et seq.*

315. Relator repeats and realleges the allegations set forth in paragraphs 1 through 314 as if fully set forth herein.

316. This is a claim for treble damages and penalties against Defendant Abiomed under the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1, *et seq.*

317. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Rhode Island, in violation of Rhode Island law.

318. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Rhode Island to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Rhode Island law.

319. The State of Rhode Island – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

320. By reason of Defendant Abiomed's conduct, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

321. Pursuant to Rhode Island law, the State of Rhode Island is entitled to three times the amount of actual damages, plus the maximum penalty of \$10,000, for each

and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

322. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by Rhode Island law, Relator is entitled to a "relator's share" of any recovery obtained by the State of Rhode Island (and/or the federal government) as a result of this claim.

COUNT XXVII

Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-181, *et seq.*

323. Relator repeats and realleges the allegations set forth in paragraphs 1 through 322 as if fully set forth herein.

324. This is a claim for treble damages and penalties against Defendant Abiomed under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181, *et seq.*

325. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Tennessee, in violation of Tennessee law.

326. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Tennessee to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Tennessee law.

327. The State of Tennessee – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant’s conduct as alleged herein.

328. By reason of Defendant Abiomed’s conduct, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

329. Pursuant to Tennessee law, the State of Tennessee is entitled to three times the amount of actual damages, plus the maximum penalty of \$25,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

330. In addition, Relator is entitled to his costs of suit and attorneys’ fees incurred in bringing this action. And, as provided by Tennessee law, Relator is entitled to a “relator’s share” of any recovery obtained by the State of Tennessee (and/or the federal government) as a result of this claim.

COUNT XXVIII

Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. § 36.001, *et seq.*

331. Relator repeats and realleges the allegations set forth in paragraphs 1 through 330 as if fully set forth herein.

332. This is a claim for treble damages and penalties against Defendant Abiomed under the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.001, *et seq.*

333. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Texas, in violation of Texas law.

334. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Texas to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Texas law.

335. The State of Texas – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

336. By reason of Defendant Abiomed's conduct, the State of Texas has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

337. Pursuant to Texas law, the State of Texas is entitled to three times the amount of actual damages, plus the maximum penalty of \$10,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

338. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by Texas law, Relator is entitled to a "relator's share" of any recovery obtained by the State of Texas (and/or the federal government) as a result of this claim.

COUNT XXIX
Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.1, *et seq.*

339. Relator repeats and realleges the allegations set forth in paragraphs 1 through 338 as if fully set forth herein.

340. This is a claim for treble damages and penalties against Defendant Abiomed under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1, *et seq.*

341. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the Commonwealth of Virginia, in violation of Virginia law.

342. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the Commonwealth of Virginia to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Virginia law.

343. The Commonwealth of Virginia – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

344. By reason of Defendant Abiomed's conduct, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

345. Pursuant to Virginia law, the Commonwealth of Virginia is entitled to three times the amount of actual damages, plus the maximum penalty of \$11,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

346. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by Virginia law, Relator is entitled to a "relator's share" of any recovery obtained by the Commonwealth of Virginia (and/or the federal government) as a result of this claim.

COUNT XXX

Washington Medicaid Fraud False Claims Act

Wash. Rev. Code § 74.66.020, *et seq.*

347. Relator repeats and realleges the allegations set forth in paragraphs 1 through 346 as if fully set forth herein.

348. This is a claim for treble damages and penalties against Defendant Abiomed under the Washington Medicaid Fraud False Claims Act, Wash. Rev. Code § 74.66.020, *et seq.*

349. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Washington, in violation of Washington law.

350. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Washington to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Washington law.

351. The State of Washington – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant’s conduct as alleged herein.

352. By reason of Defendant Abiomed’s conduct, the State of Washington has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

353. Pursuant to Washington law, the State of Washington is entitled to three times the amount of actual damages, plus the maximum penalty of \$11,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

354. In addition, Relator is entitled to his costs of suit and attorneys’ fees incurred in bringing this action. And, as provided by Washington law, Relator is entitled to a “relator’s share” of any recovery obtained by the State of Washington (and/or the federal government) as a result of this claim.

COUNT XXXI

**Wisconsin False Claims for Medical Assistance Law
Wis. Stat. § 20.931, *et seq.***

355. Relator repeats and realleges the allegations set forth in paragraphs 1 through 354 as if fully set forth herein.

356. This is a claim for treble damages and penalties against Defendant Abiomed under the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931, *et seq.*

357. By virtue of the conduct described above, Defendant Abiomed knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the State of Wisconsin, in violation of Wisconsin law.

358. By virtue of the conduct described above, Defendant Abiomed knowingly made, used, or caused to be made or used, false records or statements to induce the State of Wisconsin to pay or approve false or fraudulent claims, and/or that were material to such false or fraudulent claims, in violation of Wisconsin law.

359. The State of Wisconsin – unaware of the falsity of the records, statements, and claims (i) made, used, or presented, or (ii) caused to be made, used, or presented, by Defendant Abiomed – paid and continues to pay claims that would not be paid but for Defendant's conduct as alleged herein.

360. By reason of Defendant Abiomed's conduct, the State of Wisconsin has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

361. Pursuant to Wisconsin law, the State of Wisconsin is entitled to three times the amount of actual damages, plus the maximum penalty of \$10,000, for each and every false or fraudulent claim, record, or statement (i) that was made, used, or presented, or (ii) that was caused to be made, used, or presented, by Defendant Abiomed, as alleged herein.

362. In addition, Relator is entitled to his costs of suit and attorneys' fees incurred in bringing this action. And, as provided by Wisconsin law, Relator is entitled to a "relator's share" of any recovery obtained by the State of Wisconsin (and/or the federal government) as a result of this claim.

CLAIMS ON BEHALF OF RELATOR PERSONALLY

COUNT XXXII

Federal False Claims Act - Retaliation
31 U.S.C. § 3730(h)

363. Relator repeats and realleges the allegations set forth in paragraphs 1 through 362 as if fully set forth herein.

364. As set forth in detail above, Relator's employer Defendant Abiomed harassed, retaliated, and discriminated against Relator by terminating his employment in response to his lawful conduct involving potential violation(s) of the Federal False Claims Act by Defendant. By those actions, Abiomed violated 31 U.S.C. § 3730(h) of the FCA, which, *inter alia*, prohibits retaliation against an employee who raises concerns to his employer about possible FCA violations by the employer.

365. Defendant Abiomed retaliated against Relator because, *inter alia*, he raised his concerns about the expense reports of Defendant's sales reps that reflected lavish

expenditures for “wining and dining” physicians and/or other health care workers who purchased, or influenced the decision to purchase, Defendant’s products. In doing so, Relator was attempting to stop practices that led to the presentation of false claims to the United States. Any other ground for terminating Relator’s employment, or otherwise disciplining him, was pretextual. Accordingly, Defendant Abiomed discharged, harassed, and discriminated against Relator on account of conduct protected by 31 U.S.C. § 3130(h). Such conduct constituted retaliatory conduct in violation of said statute.

366. Defendant’s unlawful conduct has caused damage to Relator in the form of, *inter alia*, lost earnings (past and future – including two times Relator’s back pay), lost benefits (*e.g.*, medical, dental, vision, cellphone, car allowance), lost 401(k) and stock purchase benefits, and emotional distress. Relator is entitled to monetary damages from Defendant to compensate him for the harms he has suffered, plus legal interest on those damages, and Relator’s costs of suit and attorneys’ fees, all to be paid by Defendant.

COUNT XXXIII
Wrongful Termination in Violation of Public Policy
Massachusetts Law

367. Relator repeats and realleges the allegations set forth in paragraphs 1 through 366 as if fully set forth herein.

368. Defendant Abiomed unlawfully terminated Relator’s employment in retaliation for his engaging in activity required by the law and/or for refusing to do

what the law forbids. Thus, under Massachusetts law, Defendant wrongfully terminated Relator in violation of public policy.

369. Defendant's unlawful conduct has caused damage to Relator in the form of, *inter alia*, lost earnings (past and future), lost benefits (*e.g.*, medical, dental, vision, cellphone, car allowance), lost 401(k) and stock purchase benefits, and emotional distress. Relator is entitled to monetary damages from Defendant to compensate him for the harms he has suffered, plus legal interest on those damages, and Relator's costs of suit and attorneys' fees, all to be paid by Defendant.

370. Furthermore, Defendant's conduct was so outrageous and egregious that Relator should be awarded punitive damages against Defendant.

COUNT XXXIV

Violation of Mass. Gen. Laws, ch. 149 § 185B

371. Relator repeats and realleges the allegations set forth in paragraphs 1 through 370 as if fully set forth herein.

372. Relator disclosed to his supervisor in writing an activity that he reasonably believed to be in breach of a law, rule, or regulation promulgated by law, and which he reasonably believed to pose a risk to public health, safety, or the environment. In so reporting the activity, Defendant Abiomed had a reasonable opportunity to correct the activity.

373. Relator reasonably believed that reporting the activity was an emergency because the lives of patients were at stake.

374. Defendant Abiomed has taken retaliatory action against Relator in violation of Mass. Gen. Laws, ch. 149 § 185(b).

375. Defendant's unlawful conduct has caused damage to Relator in the form of, *inter alia*, lost earnings (past and future), lost benefits (*e.g.*, medical, dental, vision, cellphone, car allowance), lost 401(k) and stock purchase benefits, and emotional distress. Relator is entitled to monetary damages from Defendant to compensate him for the harms he has suffered, plus legal interest on those damages, and Relator's costs of suit and attorneys' fees, all to be paid by Defendant.

376. Furthermore, Defendant's conduct was so outrageous and egregious that Relator should be awarded punitive damages against Defendant.

CONCLUSION

WHEREFORE, Relator Max Bennett, on behalf of the United States, the Plaintiff States, and the District, and on his own behalf, hereby prays that this Court:

1. Enter judgment against Defendant Abiomed holding it liable for three times the amount of damages sustained by the United States because of Defendant's conduct;
2. Enter judgment against Defendant Abiomed holding it liable for a civil penalty of \$11,000 for each violation of the Federal False Claims Act committed by Defendant;
3. Enter judgment against Defendant Abiomed holding it liable for three times the amount of damages sustained by the Plaintiff States and the

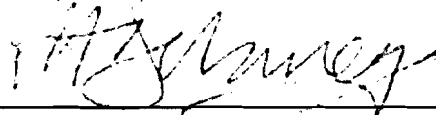
District because of Defendant's conduct, as provided for under the false claims acts of the Plaintiff States and the District;

4. Enter judgment against Defendant Abiomed holding it liable for the maximum civil penalties permitted for each violation of the false claims acts of the Plaintiff States and the District;
5. Enter judgment against Defendant Abiomed awarding Relator a percentage of the proceeds recovered by the United States as a result of this action in accordance with 31 U.S.C. § 3730(d);
6. Enter judgment against Defendant Abiomed awarding Relator a percentage of the proceeds recovered by the Plaintiff States and the District as a result of this action in accordance with the false claims acts of the Plaintiff States and the District;
7. Enter judgment against Defendant Abiomed awarding Relator his costs of suit and attorneys' fees for prosecuting this action in accordance with 31 U.S.C. § 3730(d) and similar provisions in the false claims acts of the Plaintiff States and the District;
8. With respect to Relator's claim pursuant to 31 U.S.C. § 3730(h), enter judgment against Defendant Abiomed awarding Relator all available damages and relief against Defendant including, without limitation: two times the amount of back pay he would have earned but for the retaliation; front pay; damages for lost benefits (e.g., medical, dental, vision, cellphone, car allowance); damages for lost 401(k) and stock

purchase benefits; damages for emotional distress; compensation for all special damages he has sustained as a result of Defendant's discrimination and harassment; legal interest on all of the foregoing amounts; and his costs of suit and attorneys' fees for prosecuting his personal "h" claim;

9. With respect to Relator's employment claims under Massachusetts law (Counts XXXIII & XXXIV), enter judgment against Defendant Abiomed awarding Relator all available damages and relief against Defendant including, without limitation: back pay; front pay; damages for lost benefits (*e.g.*, medical, dental, vision, cellphone, car allowance); damages for lost 401(k) and stock purchase benefits; damages for emotional distress; compensation for all special damages he has sustained as a result of Defendant's discrimination and harassment; legal interest on all of the foregoing amounts; punitive damages; and his costs of suit and attorneys' fees for prosecuting his state-law employment claims; and
10. Enter judgment against Defendant Abiomed awarding any and all other relief that the Court finds to be just and equitable.

Respectfully submitted,



Dated: July 25, 2014

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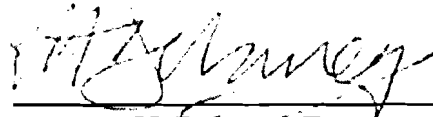
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CERTIFICATE OF SERVICE

I, Royston H. Delaney, hereby certify that on July 25, 2014, a copy of the foregoing was served on the list of persons below via United States mail postage prepaid.

Dated: July 25, 2014



Royston H. Delaney, Esq.

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